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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,265	12/10/2001	Yumio Kudo	1110-0305P	6012

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EXAMINER
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DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/009,265

Applicant(s)

KUDO ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 December 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,6,7                      6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Regarding claim 4, the parenthesis renders the claim indefinite because it is unclear whether the limitations in the parenthesis are part of the claimed invention. See MPEP § 2173.05.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe et al. (U.S. Patent 6,368,629) in view of Lida (EPO 0284039).

The claimed invention is directed to compositions comprising a compound having a disulfide bond and a polymer, and products and systems comprising said compositions.

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Watanabe et al. provides a system for releasing a drug in the colon, said system comprising a drug coated with an organic acid-soluble polymer material and a saccharide, and further coated with an enteric coating polymer (See col. 4, line 46 to col. 6, line 3). Watanabe et al. teaches that the saccharide is degraded by enterobacteria in the lower gastrointestinal tract and can be a polysaccharide (See col. 7, lines 26-34) and includes Eudragit E (dimethylaminoethyl methacrylate-methyl methacrylate-butyl methacrylate copolymer) and chitosan as specific examples of polymers used in the invention (See col. 9, lines 20-24). Watanabe et al. teaches that the polymer may contain a release-controlling material, such as Eudragit RS and ethyl cellulose (See col. 9, lines 24-50). Watanabe et al. teaches that the preparation may be in any dosage form, such as tablets, granules, powders and capsules (See col. 12, lines 4-6).

Thus, Watanabe et al. discloses formulations comprising a material degraded by enterobacteria, which can be a polysaccharide, polymer B, a substance that control disintegration and enteric coating, as claimed in the instant application. Watanabe et al. is deficient in the fact, that it does not include a compound having a disulfide bond in the formulations of the invention.

Lida discloses slow-release pharmaceutical compositions comprising a slow-release rendering additive, specifically cystine (See p. 2, line 52 to p. 3, line 3). Lida teaches that the composition can be used with any drug, the layer containing the active ingredient may be compressed with a layer containing no active ingredient, the mixed powder may be mixed with a binder, and enteric granules may be prepared by coating the first granulate with an enteric polymer (See p. 3, line 51 to p. 4, line 13). Additionally, Lida teaches that granules may be compressed into tablets, which

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may be coated with an enteric coating and provided with a sugar coating, or formed into capsules (See p. 4, lines 14-29).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the formulations disclosed by Watanabe et al., by including cystine as slow-release agent, to assure release of the drug in the lower gastrointestinal tract. The expected result would have been successful compositions and formulations for the controlled release of drugs in the colon or intestine. Because of the teachings of Lida, that formulations comprising a layer comprising cystine and an active ingredients can be combined with additional ingredients and further coated with enteric polymers, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

6. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plate` et al. (U.S. Patent 6,004,583).

Plate` et al. provides a composition comprising a water-swellaable polymer, which is chemically modified with an agent that reduces degradation of drugs, and a drug and includes dimethylaminoalkyl methacrylate and chitosan among the polymers used in the invention (See col. 7, line 36 to col. 9, line 15). Plate` et al. includes additional swellaable polymers as useful in the invention, such as agar, cellulose and pectin (See col. 11, lines 46-67). Plate` et al. teaches that the polymer must be modified with a material which contains a proteolytic inhibitor and a

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binding agent, specifically ovomucoid, and the thiol group of cystine from the protein inhibitor can be coupled to the polymer (See col. 17, line 20 to col. 18, line 28). Plate` et al. teaches that the compositions of the invention may be administered as tablets or capsules, which are enterically coated (See col. 20, lines 3-10).

The patent provides the general teachings that the formulations of the invention comprise the modified polymer and the drug, without specifying whether the drug is mixed or coated with the polymer of the invention. However, one of ordinary skill in the art would have been able to determine the best formulation by routine experimentation and clinical trials.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Plate` et al. to device a system for drug delivery in the lower gastrointestinal tract. The expected result would have been successful compositions and formulations for the controlled release of drugs in the colon or intestine. Because of the teachings of Plate` et al., that formulations comprising a swellable polymer modified to be coupled to cystine and an active ingredients can be combined with additional ingredients and further coated with enteric polymers, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

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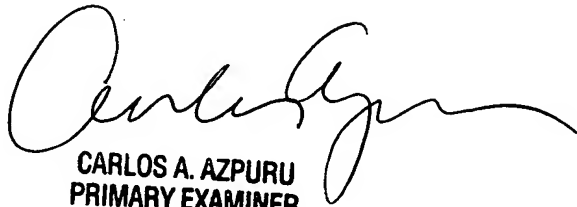
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

*SNB*

February 7, 2003

  
CARLOS A. AZPURU  
PRIMARY EXAMINER  
GROUP 1500